

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/802,166
Inventor(s) : James Robert Schwartz et al.
Filed : 03/17/2004
Art Unit : 1616
Examiner : Ernst V. Arnold
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Title : COMPOSITION COMPRISING ZINC-CONTAINING LAYERED
MATERIAL WITH A HIGH RELATIVE ZINC LABILITY

DECLARATION OF JAMES R. SCHWARTZ UNDER 37 CFR 1.132

Commissioner for Patents
PO Box 1450
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Dear Sirs:

I, James Robert Schwartz, hereby declare and say the following:

1. I have been a full-time employee of The Procter & Gamble Company for 23 years and my current position with the company is Research Fellow, P&G Beauty. I hold a B.A. in Chemistry from Kenyon College, 1982 and a PhD in Chemistry from the University of Illinois, 1986.
2. I am one of the named inventors on the above-entitled application and am familiar with the December 22, 2010 Office Action in this application.
3. The claimed invention in the above-entitled application:

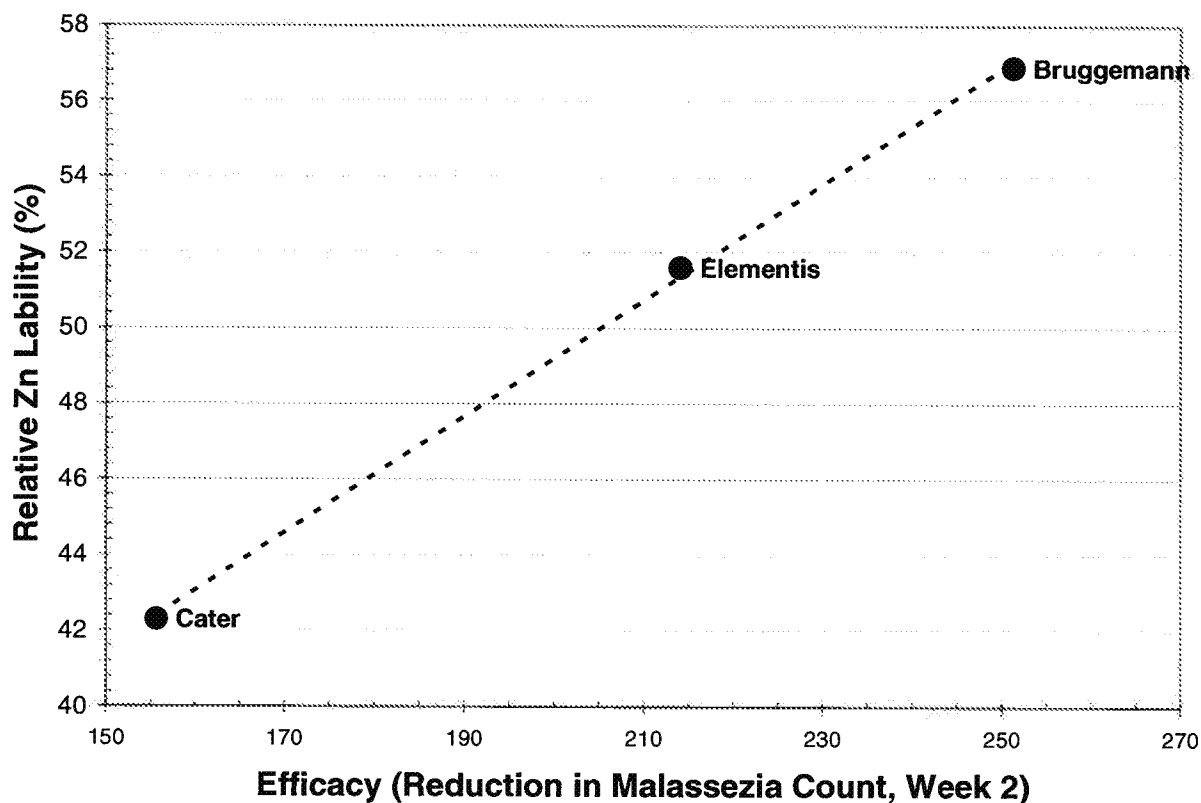
A composition comprising:

- a) from 0.001% to 5 % of a zinc-containing layered material wherein the zinc-containing layered material is an impurity containing basic zinc carbonate from 10 % to 50% of a surfactant including a surfactant with an anionic functional group;
 - b) from 0.01% to 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the impurity containing basic zinc carbonate has a relative zinc lability of greater than 15% and further wherein the ratio of surfactant to impurity containing basic zinc carbonate is greater than or equal to 2 to 1.
4. To establish the impact that changes in zinc lability of basic zinc carbonate materials has on efficacy, the IMAC data from Study AD-50 was correlated to measured zinc lability reported in the present invention.
- Data from the In Vivo Malassezia Automated Counting (IMAC) method measures the ability of an anti-dandruff product to reduce the population of Malassezia yeast on the scalp. There is a very strong relationship between reduction in Malassezia levels and resultant clinical efficacy (reduction in flake symptoms). Thus IMAC Malassezia reduction is a proxy measurement for anti-dandruff efficacy.
5. In IMAC Study AD-50, shampoo prototypes that differed only in the source of the basic zinc carbonate were evaluated for in vivo Malassezia reduction capability. This data is tabulated below in comparison to the zinc lability data for basic zinc carbonate materials of different origin reported in the present invention.

Table 1.

Source of Material	Relative Zinc Lability (%)	IMAC Efficacy (Reduction in Malassezia Count)
Bruggemann	56.9	251.2
Cater	42.3	155.7
Elementis	51.6	214.1

GRAPH 1




6. The data indicates a strong correlation between zinc lability and product efficacy, as expected from the mechanistic understanding: zinc lability is a measure of the ability of a material to release zinc ions.

Such differences of basic zinc carbonate without impurities (monophasic such as Cater and Elementis) vs. impurity containing basic zinc carbonate (e.g. Bruggemann) are important to the behavior of basic zinc carbonate, as the higher purity materials (closer to monophasic) have lower IMAC Efficacy (Reduction in Malassezia Count), as demonstrated in Table 1 and Graph 1.

7. In summary, this data demonstrates that Bruggemann-type basic zinc carbonate materials, which are impurity containing, are an important attribute of the claimed invention to achieve high performance.

8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that the statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application of any patent issued thereon.



James Robert Schwartz

Dated: 21 Jun 2011

18 U.S.C §1001 Statements or Entries Generally

Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry shall be fined no more than \$10,000 or imprisoned not more than five years, or both.